



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/568,261

11/01/2006

Gordon D. Ross

3593.1000-003

9677

21005

7590

06/03/2010

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

530 VIRGINIA ROAD

P.O. BOX 9133

CONCORD, MA 01742-9133

EXAMINER

DAVIS, DEBORAH A

ART UNIT

PAPER NUMBER

1655

MAIL DATE

DELIVERY MODE

06/03/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/568,261	Applicant(s) ROSS ET AL.	
	Examiner DEBORAH A. DAVIS	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2-13-06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-7 in the reply filed on 2-12-10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jamas et al (US 5,488,040).

The claims are drawn to a method of enhancing glucan-mediated committed stem cell proliferation and expansion after injury via the complement system pathway, comprising administering to an individual a therapeutically effective orally bioavailable amount of whole glucan particles.

The reference of Jamas et al. beneficially teaches that soluble β -glucans can be administered orally (bioavailable) to treat animals or humans (individuals) who are at risk of infection due to surgery, injury, illness radiation or chemotherapy and also includes wound healing healing (i.e. tissue repair). In the background of the invention,

Art Unit: 1655

Jamas discloses that various preparations of both particulate and soluble β -glucans have been tested in animal models to show the hemopoietic effects of increased peripheral blood leukocyte counts and bone marrow that reflect the increased numbers of progenitor cells (proliferation), and splenic pluripotent stem cells (column 1, lines 62-67, column 2, lines 1-13, column 4, lines 1-16, e.g). Data from invitro or animal testing is sufficient to support that the process or product has this therapeutic utility in humans (see M.P.E.P. 2107.03). The instant specification (see page 3) states that committed stem cells can include progenitor cells. Therefore the splenic pluripotent stem cells and progenitor cells of Jamas read on committed stem cells, as claimed. Although the reference of Jamas does not teach the administration of whole glucan particles (WGP) in its method, the soluble β -glucans are made from WGP and according to the teachings in the background of the reference, both the soluble and WGP will increase (proliferate) the number of stem cells. With respect to the limitation of claims 1-7 that recites that glucan activates and enhances stem cell proliferation via complement system pathway would be inherent upon the administration of β -glucan taught by Jamas. The instant claims describes a mechanism that applicant has elucidated but such a mechanism would be inherent because the method steps of administering β -glucan are the same as instantly claimed and therefore would travel the same complement pathway.

The reference of Jamas does not teach wherein the committed stem cells are selected from the group consisting of stem cells from liver, heart, muscle, kidney and neural tissue.

Art Unit: 1655

However, the reference of Patchen et al. beneficially teaches a method of inducing mobilization of peripheral blood precursor and progenitor cells from hematopoietic organs of the body such as bone marrow, liver or spleen by administering aqueous soluble β -glucan to a patient. The β -glucan can be administered orally, paternally, and intravenously (column 4, lines 61-67, e.g.). Once these cells are mobilized and expanded (proliferation) they are reinfused into the individuals that have gone through chemotherapy or radiation therapy (see column 5, lines 20-67, column 6, lines 1-17, e.g.).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the references of Jamas in view of Patchen based on their beneficial teachings of administering β -glucan to an individual for progenitor cell proliferation after chemotherapy. It would have been further obvious to select cells from organs such as the liver, or spleen because they can become damaged through chemotherapy and therefore need to be replenished.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH A. DAVIS whose telephone number is (571)272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

Art Unit: 1655

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Deborah A. Davis
Patent Examiner, AU 1655
May 2010

/Christopher R. Tate/
Primary Examiner, Art Unit 1655